

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*,
ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., *et al.*,

Defendants.

Civil Action No. 19-cv-12107-MEF-SDA

SPECIAL MASTER ORDER

THIS MATTER having come before the undersigned Special Master appointed by Order entered on March 18, 2024 (ECF No. 331); and the Order providing that the Special Master “shall oversee the schedule for completion of discovery, and all discovery disputes and motions related thereto, pursuant to procedures for practice that the Special Master may establish and modify as necessary”, *id.* at 2, ¶ 2; and the Special Master, in order to address and resolve the respective discovery disputes between Relator Zachary Silbersher (“Relator”) and Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson (collectively, “Defendants”, and together with Relator, “Parties”), having entered an Order on April 12, 2024 (ECF No. 337) setting deadlines for submissions relating to “unresolved discovery issues”, *id.* at 1, ¶¶ 2-3; and the Special Master having considered the issues, arguments, and positions with respect to the remaining disputes concerning Defendants’ Responses to Relator’s Second Interrogatories (specifically, Interrogatory Nos. 16, 17, 23, 24, and 25), Defendants’ Responses to Relator’s Sixth Requests for Production (specifically, Request for Production Nos. 88 and 89), and Defendants’ Responses to Relator’s First Requests for Admissions (specifically, Request for Admission Nos. 1-4, 6, 7, 9, 11-14, and 16-20), as set forth

in: (1) the Parties' joint letter of March 29, 2024 (ECF No. 336); (2) Relator's submission of April 26, 2024 (ECF No. 340); (3) Defendants' response of May 3, 2024 (ECF No. 349); (4) Relator's submission of May 10, 2024 (ECF No. 350); (5) Defendants' response of May 17, 2024 (ECF No. 352); and Relator's requests for relief as set forth in the Parties' joint letter of March 29, 2024, Relator's submission of April 26, 2024, and Relator's submission of May 10, 2024 (ECF Nos. 336, 340, and 350), all together constituting an application to compel Defendants to provide supplemental responses to Relator's multiple discovery requests ("Application"); and good cause appearing for the entry of this order

IT IS on this **22nd** day of **October 2024 ORDERED** as follows:

1. Relator's Application is **GRANTED IN PART, AND DENIED IN PART**.
2. As to Relator's Interrogatory No. 16, Defendants are directed to serve an amended response consistent with this Opinion within twenty (20) days of the entry of this Order.
3. As to Relator's Interrogatory No. 17, Relator may serve an amended Interrogatory No. 17 identifying a single Request for Admission as to which Relator seeks all facts on which an unqualified admission by Defendants is based within fourteen (14) days of the entry of this Order. Defendants shall serve a response to any such amended Interrogatory No. 17 within fourteen (14) days of service of amended Interrogatory No. 17.
4. As to Relator's Interrogatory No. 23, Defendants are directed to serve an amended response consistent with this Opinion within twenty (20) days of the entry of this Order.
5. As to Relator's Interrogatory No. 24, Defendants are directed to serve an amended response consistent with this Opinion within twenty (20) days of the entry of this Order.
6. As to Relator's Interrogatory No. 25, Defendants are directed to serve an amended response consistent with this Opinion within twenty (20) days of the entry of this Order.

7. As to Relator's Request for Admission No. 1, Relator's request for relief is denied.

8. As to Relator's Request for Admission Nos. 2 through 4, Defendants are directed to serve amended responses as to Request Nos. 2, 3, and 4 consistent with this Opinion within twenty (20) days of the entry of this Order.

9. As to Relator's Request for Admission No. 6, Relator may serve an amended Request for Admission No. 6 that includes a definition of the phrase, "real parties in interest" (or "real party in interest") within fourteen (14) days of the entry of this Order. Defendants shall serve a response to any such amended Request for Admission No. 6 which response shall be based on the definition of "real parties in interest" (or "real party in interest") within fourteen (14) days of service of amended Request for Admission No. 6.

10. As to Relator's Request for Admission Nos. 7 and 9, Defendants are directed to serve amended responses to these requests consistent with this Opinion within twenty (20) days of the entry of this Order.

11. As to Relator's Request for Admission Nos. 11 through 14 and Nos. 16 through 20, Relator's requests for relief are denied.

12. As to Relator's Request for Production No. 88, Relator's requests for relief is denied.

13. As to Relator's Request for Production No. 89, Defendants are directed to either: (1) represent to Relator that all non-privileged documents and communications responsive to this request have been searched for and produced; or alternatively, (2) conduct a search for all non-privileged documents and communications responsive to this request that have not been produced in discovery, and produce all such responsive materials. Defendants shall comply with this provision and directive within thirty (30) days of the entry of this Order.

SPECIAL MASTER DECISION

The Special Master presumes the parties are well acquainted with the pertinent facts and procedural history of this matter.

Before the Special Master are Relator's numerous requests for relief with respect to Defendants' Responses to Relator's Second Interrogatories (Interrogatory Nos. 16, 17, 23, 24, and 25), Defendants' Responses to Relator's Sixth Requests for Production (Request for Production Nos. 88 and 89), and Defendants' Responses to Relator's First Set of Requests for Admissions (Request for Admission Nos. 1-4, 6, 7, 9, 11-14, and 16-20). The Parties have made several submissions to the Special Master concerning the foregoing discovery requests and the adequacy of Defendants' responses and objections. (ECF Nos. 336, 340, 349, 350, and 352.) As stated in his submissions, Relator "moves for relief to address Defendants' deficient responses to certain of Relator's most recent written discovery requests[.]"¹ (ECF No. 340, p. 1.) For the reasons stated herein, Relator's Application is granted in part, and denied in part.

I. Defendants' Responses to Relator's Second Set of Interrogatories²

Relator claims Defendants' responses to his Interrogatory Nos. 16, 17, 23, 24, and 25 are deficient. The Parties' respective positions as to each of these interrogatories and related issues concerning Defendants' responses and objections will be addressed in turn.

Interrogatory No. 16. According to Relator, this interrogatory asks Defendants to describe the roles, rights, and responsibilities of each corporate entity that participated in bringing Zytiga

¹ The Parties' submissions did not include copies of Relator's Second Interrogatories, Relator's Sixth Requests for Production, Relator's First Set of Requests for Admission, or Defendants' Responses and Objections to these discovery requests.

² Despite being addressed in the Parties' joint letter of March 29, 2024, Relator's submission of April 26, 2024 omits discussion of Defendants' Responses to Interrogatory Nos. 9 and 15. (ECF No. 340, pp. 1-5.) The Special Master therefore presumes issues as to these responses are now moot, or have been resolved.

to market. (ECF No. 336, p. 2; ECF No. 340, p. 2.) Relator claims Defendants' response is deficient as it states that Johnson & Johnson is the parent company to the other Janssen Defendants, and that the Executive Committee of Johnson & Johnson is the principal management group responsible for strategic operations and allocation of the resources of Johnson & Johnson. (ECF No. 336, p. 2; ECF No. 340, p. 3.) Relator also submits that Defendants waived their objections to the interrogatories at issue in Relator's Application because Defendants' responses to the interrogatories were served seven days late. (ECF No. 340, p. 2.)

In response, Defendants dispute that they waived their objections based on the late service of their responses to the interrogatories and assert Relator was not prejudiced by any delay. (ECF No. 349, pp. 11, 12.) Further, Defendants contend this interrogatory is cumulative of Relator's other requests, including Request for Admission Nos. 1 through 4, and that Defendants nevertheless provided a complete response to Interrogatory No. 16.³ Defendants also question Relator's need for a "detailed explanation of all functions" by each Defendant. *Id.* at 13.

Interrogatory No. 23. According to Relator, this interrogatory asks Defendants to describe the ownership, control, and corporate relationships between and among Defendants and any affiliates involved in the research, development, marketing and sale of Zytiga. Relator claims Defendants' response is deficient as it states that Johnson & Johnson is the parent company to the other Janssen Defendants. (ECF No. 336, p. 2; ECF No. 340, p. 3.)

³ According to Defendants, their response to Interrogatory No. 16 is as follows: "Johnson & Johnson is a publicly traded company that has no parent, and which wholly owns numerous operating companies that operate worldwide. Those wholly-owned entities include Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research and Development, LLC, each of which has been named as a defendant in this action. The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company." (ECF No. 349, p. 13.)

In response, Defendants once again contend this interrogatory is cumulative of Relator's other requests, including Request for Admission Nos. 1 through 4, and note they provided an appropriate response "substantially identical" to their response to Interrogatory No. 16. Defendants have admitted that J&J "sold Zytiga" and are foregoing any argument that Relator failed to name a necessary J&J party. Thus, they maintain a further response is "unwarranted".

Interrogatory No. 24. According to Relator, this interrogatory asks Defendants to identify legal and factual contentions relating to the delay of generic entry by obtaining, listing, and asserting the '438 Patent. (ECF No. 336, p. 3; ECF No. 340, p. 4.) Relator claims Defendants objected on several grounds, including that the interrogatory was premature and improper.

In response, Defendants maintain this contention interrogatory was served more than three months before the close of fact discovery and thus is untimely. Defendants submit that this interrogatory should be re-served "at the proper time." (ECF No. 349, p. 15.)

Interrogatory No. 25. According to Relator, this interrogatory asks Defendants to identify the materiality of Defendants' exclusion of generic competition from the government's (or Plaintiff States') decision to pay or reimburse for Zytiga. (ECF No. 336, p. 3; ECF No. 340, p. 4.) Relator claims Defendants objected on several grounds, including that the interrogatory was premature and improper.

In response, Defendants maintain this contention interrogatory was served more than three months before the close of fact discovery and thus is untimely. Defendants submit that this interrogatory should be re-served "at the proper time." (ECF No. 349, p. 15.)

Interrogatory No. 17. Relator claims Defendants' response to Interrogatory No. 17 is deficient. Interrogatory No. 17 asks, "[f]or each of your responses to the Requests for Admission served with these Interrogatories that is not an unqualified admission, state all facts upon which

you base your response.” (ECF No. 350, pp. 2, 3.) According to Relator, Defendants objected to this interrogatory because it consists of subparts which exceed the number of permissible interrogatories. Relator claims Defendants waived any objection to this interrogatory by failing to respond within the period set forth under Rule 33. Relator maintains that this interrogatory is proper in any event. *Id.* at 3.

In response, Defendants contend Interrogatory No. 17 is improper because it “attempts to transform each of Relator’s Requests for Admission into an interrogatory.” (ECF No. 352, p. 4.) As such, Defendants submit, Relator’s Interrogatory No. 17 violates Rule 33(a)’s limitation on the default number of interrogatories a party may serve as this interrogatory essentially constitutes 25 separate requests.

II. Defendants’ Responses to Relator’s First Requests for Admission

Relator claims Defendants’ responses to Request for Admissions Nos. 1-4, 6, 7, 9, 11-14, and 16-20 are deficient. The Parties’ respective positions as to each of these requests and related issues concerning Defendants’ responses and objections will be addressed in turn.

Request for Admission Nos. 1 through 4. As to Request for Admission Nos. 1 through 4, Relator claims these Requests seek an admission “that each separate Defendant ‘exercised control over the sale of Zytiga[.]’” (ECF No. 340, p. 6.) Relator notes that Defendants’ Response to Request No. 1 consists of an admission that “[J&J] sold Zytiga, including by and through its subsidiaries[.]” but that Defendants’ Responses to Request Nos. 2 through 4 refer back to the Response to Request No. 1. As to Request No. 1, Relator claims he is “entitled to know whether [J&J] exercised control over the sale of Zytiga.” *Id.* at 7. Similarly, as to Request Nos. 2 through 4, Relator claims he is “entitled to know whether ... the other Defendants exercised control over the sale of Zytiga.” *Id.* Thus, Relator claims Defendants have not responded as to whether the

other Defendants (aside from Johnson & Johnson) exercised control over the sale of Zytiga, or the specific subsidiaries through which Johnson & Johnson sold Zytiga. *Id.*

In response, Defendants contend Relator's response was appropriate: "[J&J] sold Zytiga, including by and through its subsidiaries, for use in combination with prednisone in the United States from April 28, 2011 through the present time." (ECF No. 349, p. 8.) Defendants maintain their straightforward response is sufficient and that Relator has refused to define "exercised control over ... sales" despite efforts to meet and confer on the issue. *Id.* Defendants submit Relator's Application as to Request for Admission Nos. 1 through 4 should be denied.

Request for Admission No. 6. As to Request No. 6, which asks Defendants to admit whether they are "real parties in interest in the '438 Patent, Relator claims Defendants admitted that "Janssen Oncology, Inc. was the assignee listed on the '438 Patent" but "did not otherwise admit or deny" Request No. 6. And Relator notes that he alleges that Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC filed certifications that they were real parties in interest for the '438 Patent and that they were subsidiaries of Johnson & Johnson (likewise a party in interest in the '438 Patent application). (ECF No. 340, p. 7.) Thus, Relator seeks a "straightforward admission or denial" as to whether each of the Defendants is a real party in interest to the '438 Patent. *Id.* at 8.

In response, Defendants contend this request is vague and ambiguous because "real parties in interest" are not defined, and Relator failed to provide a definition or further clarification despite Defendants' efforts to meet and confer on the issue. (ECF No. 349, p. 9.) Defendants maintain their response – which admits that Janssen Oncology, Inc. was the assignee listed on the '438 Patent – is sufficient, particularly given the lack of definition or clarification from Relator on the disputed phrase.

Request for Admission Nos. 7 and 9. As to Request Nos. 7 and 9, which ask Defendants to admit that “[J&J], Janssen Biotech, Janssen Oncology, and Janssen Research & Development collectively sell Zytiga pursuant to NDA No. 202379[.]” (Request No. 7), and to admit that “[J&J] arranged for the sale of Zytiga through its wholly owned subsidiaries, including the Janssen [Defendants] and their affiliates[.]” (Request No. 9), Relator claims Defendants interposed meritless objections and merely admitted that “J&J sold Zytiga, including by and through its subsidiaries[.]” (ECF No. 340, p. 8.) Relator disputes the sufficiency of Defendants’ responses and claims they are “non-responsive”.

In response, Defendants contend that the phrases “collectively sell” and “arranged for the sale” are vague and ambiguous, and that Relator has not provided a definition or clarification despite Defendants’ efforts to meet and confer on the issue. (ECF No. 349, p. 8.) Defendants add that these requests are cumulative of Request for Admission Nos. 1 through 4, and that they have provided sufficient responses to Request Nos. 7 and 9: “[J&J] sold Zytiga, including by and through its subsidiaries, for use in combination with prednisone in the United States pursuant to NDA No. 202379 from April 28, 2011 through the present time.” *Id.* at 8, 9.

Request for Admission Nos. 11 through 14 and Nos. 16 through 20. As to Request Nos. 11 through 14 and Nos. 16 through 20 which, as stated by Relator, relate to “a number of important issues in the case[.]” Relator contends Defendants objected to each of these requests as seeking an “admission of a legal conclusion.” (ECF No. 340, p. 8.) Relator submits that these requests seek factual admissions as to each Defendant’s knowledge of underlying facts, and moreover, that Rule 36(a)(1) permits requests relating to facts, the application of law to fact, or opinions about either. *Id.* at 8-9. Relator questions Defendants’ objections, including the objection that these requests call for Defendants to “assume” facts and conclusions, but notes that Defendants’ responses

include “subsequent denial[s]”. *Id.* at 9. Aside from Request No. 12⁴, Relator does not excerpt or even summarize Request Nos. 11, 13, 14, 16, 17, 18, 19, or 20.

In response, Defendants contend these requests use vague, ambiguous, overbroad, and undefined terms, and that Relator “fails to provide individualized arguments supporting these [requests]” and asks the Court to compel responses on “general grounds” based on “importance”. (ECF No. 349, p. 15.) Moreover, Defendants note they responded to each of these requests with a denial. With respect to Request for Admission No. 20 – which asks to “[a]dmit that Defendants did not disclose to the Patent Office any of the alleged factors for Zytiga’s commercial success set forth in paragraphs 84 and 87 of the Complaint” – Defendants submit this request is “unserious on its face” and that Defendants in any event denied this request. *Id.* at 16. In addition, Defendants dispute a number of terms and phrases used in these requests. *Id.*

III. Defendants’ Responses to Relator’s Sixth Requests for Production⁵

Relator claims Defendants’ responses to Request for Production Nos. 88 and 89 are deficient. The Parties’ respective positions as to both requests and related issues concerning Defendants’ responses and objections will be addressed in turn.

Request for Production No. 88. According to Relator, this request seeks documents related to indemnity agreements between and among Defendants to provide indemnity, cover costs, or

⁴ According to Relator, this request asks Defendants to “[a]dmit that during the prosecution of the ’438 Patent, each Defendant knew that Zytiga held a material competitive advantage against competitors, including, without limitation, XTANDI, because it had or was expected to have FDA approval before those competing treatments.” (ECF No. 340, pp. 8-9.)

⁵ Despite being addressed in the Parties’ joint letter of March 29, 2024, Relator’s submission of April 26, 2024 omits discussion of Defendants’ Responses to Relator’s Request for Production Nos. 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, and 100. (ECF No. 340, pp. 5-6.) The Special Master therefore presumes issues as to these responses are now moot, or have been resolved.

reimburse for any liabilities related to this action. Relator claims Defendants have refused to conduct a search for responsive documents. (ECF No. 336, p. 4; ECF No. 340, p. 5.)

In response, Defendants dispute the relevance of non-insurance indemnity agreements and submit that apportionment of liability among Defendants is “of no moment” to the merits of this dispute. (ECF No. 349, p. 10.) Defendants maintain they will not argue that Relator failed to include a necessary J&J party as a defendant to the litigation, and there are no other reasons why internal indemnity agreements are relevant. They add that Request for Production No. 88 is duplicative of a prior document request by Relator, to which Defendants timely responded and objected, without any further action on the part of Relator as to that prior request.

Request for Production No. 89. According to Relator, this request seeks contracts, agreements, and licenses between Defendants and any affiliated companies related to the development, research, manufacturing, sale, marketing and distribution of Zytiga. (ECF No. 340, p. 6.) Relator claims Defendants responded by agreeing to meet and confer and by referring to documents already produced in discovery. However, Relator maintains Defendants’ response is not sufficient as Defendants have not agreed to produce “all” responsive documents. (ECF No. 336, p. 4.)

In response, Defendants note this request is cumulative of Relator’s Request for Production No. 53, and in responding to that prior request, Defendants referred Relator to “multiple documents ... already ... produced”. (ECF No. 349, p. 11.) Defendants state Relator’s only complaint is that Defendants have not represented that “all agreements” responsive to these requests have been produced, while noting Relator failed to explain why a further comprehensive search is necessary, appropriate, or proportional.

IV. Legal Standard

a. Relevance and Scope of Discovery.

“The precise boundaries of the Rule 26 relevance standard depend upon the context of each particular action, and the determination of relevance is within the discretion of the District Court.” *Graco, Inc. v. PMC Global, Inc.*, No. 08-01304, 2011 WL 1114233, at *28 (D.N.J. Mar. 24, 2011) (citing *Barnes Found. v. Twp. of Lower Merion*, No. 96-00372, 1996 WL 653114, at *1 (E.D.Pa. 1996)). Under Rule 26, “[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.” Fed. R. Civ. P. 26(b)(1).

Courts have “broad discretion in managing requests for discovery and determining the appropriate scope of discovery.” *Falato v. Fotografixusa, L.L.C.*, No. 09-05232, 2013 WL 1846807, at *3 (D.N.J. Apr. 30, 2013) (citation omitted). “Rule 26(b)(2) vests the court with the authority to limit a party’s pursuit of otherwise discoverable information.” *Gilmore v. Jones*, No. 21-13183, 2022 WL 267422, at *2 (D.N.J. Jan. 28, 2022); *see also Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999) (“Although the scope of discovery under the Federal Rules is unquestionably broad, this right is not unlimited and may be circumscribed.”). Further, “the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that: (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in

the action; or (iii) the proposed discovery is outside the scope permitted by Rule 26(b)(1).” *King v. Verizon New Jersey, Inc.*, No. 21-11226, 2023 WL 5817126, at *4 (D.N.J. Sept. 6, 2023) (citing Fed. R. Civ. P. 26(b)(2)(C)).

b. Interrogatories

“An interrogatory may relate to any matter that may be inquired into under Rule 26(b).” Fed. R. Civ. P. 33(a)(2). “Each interrogatory must, to the extent it is not objected to, be answered separately and fully in writing under oath.” Fed. R. Civ. P. 33(b)(3). “An interrogatory response must be complete in itself, explicit, and responsive.” *V5 Technologies v. Switch, Ltd.*, 334 F.R.D. 296, 305 (D. Nev. 2019) (citations omitted). “A responding party has a duty to answer an interrogatory reasonably, in good faith, and according to the meaning the plain language of the interrogatory would naturally import.” *Sprint Solutions, Inc. v. 4 U Cell, LLC*, No. 15-00605, 2016 WL 4815101, at *3 (M.D. Fla. 2016). An evasive, misleading and incomplete response is treated as a failure to disclose, answer, or respond. *See Younes v. 7-Eleven, Inc.*, 312 F.R.D. 692, 705 (D.N.J. 2015) (citing Fed. R. Civ. P. 37(a)(4)).

c. Requests for Admission

Rule 36(a) sets forth the scope and procedure for requests for admission. *See* Fed. R. Civ. P. 36(a); *see also In re: Valeant Pharmaceuticals Int’l., Inc. Sec. Litig.*, No. 15-07658, 2021 WL 2164108, at *2-3 (D.N.J. Apr. 12, 2021) (reciting relevant provisions of Rule 36(a)). Pursuant to Rule 36(a)(1), a party may serve on any other party a request to admit “the truth of any matters within the scope of Rule 26(b)(1) relating to ... facts, the application of law to fact, or opinions about either” as well as “the genuineness of any described documents.” Fed. R. Civ. P. 36(a)(1)(A), (B).

“If a matter is not admitted, the answer must specifically deny it or state in detail why the answering party cannot truthfully admit or deny it.” Fed. R. Civ. P. 36(a)(4). “[W]hen good faith requires that a party qualify an answer or deny only a part of a matter, the answer must specify the part admitted and qualify or deny the rest.” Fed. R. Civ. P. 36(a)(4). Further, the “grounds for objecting to a request must be stated.” Fed. R. Civ. P. 36(a)(5). Rule 36(a)(6) also establishes the procedure by which a party may move to determine the sufficiency of an answer or objection. Fed. R. Civ. P. 36(a)(6).

“A request for admission should be such ‘that it could be answered yes, no, the answerer does not know, or a very simple direct explanation given as to why he cannot answer, such as in the case of privilege.’” *IBEW v. Star-Lo Electric*, No. 08-00900, 2010 WL 11530624, at *9 (D.N.J. Mar. 1, 2010) (quoting *United Coal Companies v. Powell Constr. Co.*, 839 F.2d 958, 968 (3d Cir. 1988)). To determine whether an objection is “justifiable” and to evaluate the “sufficiency” of a response to a request for admission, the court will consider the following: (1) whether the denial fairly meets the substance of the request; (2) whether good faith requires that the denial be qualified; and (3) whether any qualification which has been supplied is a good faith qualification.” *In re: Valeant Pharmaceuticals*, 2021 WL 2164108, at *3 (citing *Thalheim v. Eberheim*, 124 F.R.D. 34, 35 (D. Conn. 1988)).

“Requests for Admission ... serve two significant purposes – to facilitate proof as to issues that cannot be eliminated from the case and to narrow issues by limiting those that can be [eliminated].” *In re: Valeant Pharmaceuticals*, 2021 WL 2164108, at *3 (citing *United States v. Nicolet, Inc.*, No. 85-03060, 1989 WL 51734, at *1 (E.D.Pa. May 12, 1989)). “If [the responding parties] assert lack of knowledge or information as a reason for failing to admit or deny, [they] must certify that they made reasonable inquiry in attempt to obtain an answer and that the

information they know or can readily obtain is insufficient to enable it to admit or deny.” *IBEW*, 2010 WL 11530624, at *9 (citing Fed. R. Civ. P. 36(a)(4)).

d. Requests for Production

“A party may serve on any other party a request within the scope of Rule 26(b): to produce and permit the requesting party ... to inspect, copy, test, or sample ... documents or electronically stored information[.]” Fed. R. Civ. P. 34(a)(1)(A). The responding party may: (1) state it will permit inspection and related activities; (2) state it will produce copies of documents or copies of electronically stored information instead of permitting inspection; or (3) state with specificity the grounds for objecting to the request. Fed. R. Civ. P. 34(b)(2)(B). “Rule 34 ... permits parties to exchange requests for documents and other relevant evidence in ‘the responding party’s possession, custody, or control.’” *King*, 2023 WL 5817126, at *7 (citing Fed. R. Civ. P. 34(a)). “A party cannot produce what it does not have, and so, clearly, the court cannot compel a party to produce non-existent documents.” *Samsung Electronics America, Inc. v. Yang Kun Chung*, 321 F.R.D. 250, 259 (N.D. Tex. 2017).

e. **Special Master’s Decision**

a. Defendants’ Responses to Relator’s Second Set of Interrogatories.

As a preliminary matter, the Special Master finds there is good cause to excuse Defendants’ late service of their responses to Relator’s Second Set of Interrogatories. Rule 33(b)(4) provides that the failure to timely object may be excused for “good cause”. Fed. R. Civ. P. 33(b)(4). Relator notes that Defendants’ responses were served seven (7) days after the deadline for service. This delay is not extreme, and Defendants make the valid point that Relator suffered no prejudice by the delay. The Special Master finds good cause to excuse the relatively *de minimis* delay.

Defendants' objections are not waived on the basis that the responses (and objections) were served out of time.

Interrogatory No. 16. The Special Master finds that Defendants' response to Relator's Interrogatory No. 16, while partially responsive, remains evasive. Interrogatory No. 16 seeks a description of the roles, rights, and responsibilities of each corporate entity that participated in bringing Zytiga "to market." According to Defendants, their response to Interrogatory No. 16 is as follows: "Johnson & Johnson is a publicly traded company that has no parent, and which wholly owns numerous operating companies that operate worldwide. Those wholly-owned entities include Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research and Development, LLC, each of which has been named as a defendant in this action. The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company." (ECF No. 349, p. 13.)

The problem with this response is that it fails to specify whether J&J brought Zytiga "to market" and omits a description of the respective roles, rights, and responsibilities the various J&J entities had with regard to marketing and selling Zytiga. The response also leaves open the question of whether any other entities, whether the Janssen Defendants or otherwise, also participated in bringing Zytiga to market. This response should be supplemented to address whether J&J and/or any other Defendants brought Zytiga "to market", and what roles, rights, and responsibilities J&J and those Defendants had (if any) with respect to those marketing and sales efforts.

Interrogatory No. 23. The Special Master finds that Defendants' response to Relator's Interrogatory No. 23, while partially responsive, is likewise somewhat evasive. Interrogatory No. 23 seeks a description of the ownership, control, and corporate relationships between and among

the several Defendants and any affiliates involved in the research, development, marketing and sale of Zytiga. Defendants submit that their response to Interrogatory No. 23, which is “substantially identical” to their response to Interrogatory No. 16, is appropriate.

The Special Master has not been presented with copies of Interrogatory No. 23 or Defendants’ response to same. However, Defendants represent that their response to Interrogatory No. 23 is “substantially identical” to their response to Interrogatory No. 16 (which *has* been excerpted in Defendants’ submission). As such, while Defendants’ response to Interrogatory No. 23 is partially responsive and does identify the corporate relationships among Defendants, it fails to specify whether the Janssen Defendants or any other “affiliates” were involved in the research, development, marketing and sale of Zytiga. In this regard, the Special Master finds this response is deficient and should be supplemented appropriately.

Interrogatory No. 24. It appears that Defendants objected to this contention interrogatory because it was served three months before the close of fact discovery and thus was premature. This interrogatory asks Defendants to identify legal and factual contentions relating to the delay of generic entry by obtaining, listing, and asserting the ’438 Patent. (ECF No. 336, p. 3; ECF No. 340, p. 4.) Local Civil Rule 33.1(d) provides that “[c]ontention interrogatories shall not be served until 60 days prior to the close of fact discovery unless otherwise permitted by the Court.” There appears to be no other reason Defendants refused to respond to this interrogatory. The Special Master finds that, at this juncture of the litigation where discovery has been substantially completed, a response should be provided. Indeed, “responses to contention interrogatories will do more to advance litigation when the parties are in possession of facts and knowledge obtained from a meaningful amount of document discovery and witness testimony[.]” *Weston v. Subaru of Am., Inc.*, No. 20-05876, 2022 WL 18024222, at *4 (D.N.J. Dec. 31, 2022) (quoting *U.S. v. Bayer*

Corp., No. 05-03895, 2020 WL 13189534, at *3 (D.N.J. Apr. 16, 2020)). Defendants are directed to serve a response to Interrogatory No. 24.

Interrogatory No. 25. Similarly, it appears that Defendants objected to this contention interrogatory because it was served three months before the close of fact discovery and thus was premature. This interrogatory asks Defendants to identify the materiality of Defendants' exclusion of generic competition from the government's (or Plaintiff States') decision to pay or reimburse for Zytiga. (ECF No. 336, p. 3; ECF No. 340, p. 4.) Local Civil Rule 33.1(d) and the relevant case law are clear. Again, there appears to be no other reason Defendants refused to respond to this interrogatory. The Special Master finds that, at this juncture of the litigation, a response should be provided. Defendants are directed to serve a response to Interrogatory No. 25.

Interrogatory No. 17. The Special Master finds that Interrogatory No. 17 is overly broad and unduly burdensome. This interrogatory asks for "all facts" on which Defendants base any response to Relator's Requests for Admission that is not an unqualified admission. Because Relator served twenty-five (25) Requests for Admission, this interrogatory is potentially comprised of upwards of twenty-five (25) sub-parts—depending, of course, on exactly how many of Defendants' responses were unqualified admissions (or not). Because Relator has not obtained Defendants' consent or the Court's (or Special Master's) leave to serve more than twenty-five (25) interrogatories, this interrogatory is improper. However, the Special Master affords Relator an opportunity to amend Interrogatory No. 17 to identify a single Request for Admission as to which Relator seeks all facts on which an unqualified admission by Defendants is based. Relator may serve an amended Interrogatory No. 17 within fourteen (14) days of the entry of this Order. Defendants shall serve a response to amended Interrogatory No. 17 within fourteen (14) days of service of amended Interrogatory No. 17.

b. Defendants' Responses to Relator's First Requests for Admission.

Request for Admission Nos. 1 through 4. The Special Master finds that Defendants' responses to Request Nos. 2, 3, and 4, while partially responsive, are incomplete. Request Nos. 1 through 4 seek an admission as to whether each of the Defendants "exercised control" over the sale of Zytiga. While Defendants responded to Request No. 1 that "J&J" sold Zytiga, including by and through its subsidiaries, Defendants' responses to Request Nos. 2, 3, and 4 fail to specify whether one, some, or all of the Janssen Defendants exercised control over Zytiga sales (or not). The general reference to J&J's subsidiaries is somewhat broad. Defendants' responses to Request for Admission Nos. 2, 3, and 4 only should be amended to admit, or deny, or partially admit or deny (with appropriate qualifying language) that the other Janssen Defendants exercised any degree of control over Zytiga sales. As to the disputed phrase "exercise control over ... sales", Defendants should apply an ordinary definition with plain meaning to the terms of these requests, and if necessary, qualify its response based on Defendants' understanding of these terms.

Request for Admission No. 6. The Special Master finds that Defendants' response to Request for Admission No. 6 is sufficient because Relator failed to provide a definition or any clarification on the phrase "real parties in interest". This request asks Defendants to admit whether they are "real parties in interest" in the '438 Patent. Given that "real parties in interest" potentially carries legal significance, Defendants cannot simply apply an ordinary definition with plain meaning to this phrase. The Special Master also accepts Defendants' representation—which was not disputed by Relator—that Relator failed to furnish a definition despite Defendants' efforts to meet and confer on this request. Relator's Application as to Request for Admission No. 6 is denied.

However, Relator may serve an amended Request for Admission No. 6 that includes a definition of the phrase, "real parties in interest", within fourteen (14) days of the entry of this

Order. Defendants shall serve an amended response to any amended Request for Admission No. 6 which response shall be based on the definition of “real parties in interest”, within fourteen (14) days of service of amended Request for Admission No. 6.

Request for Admission Nos. 7 and 9. The Special Master finds that Defendants’ responses to Request for Admission Nos. 7 and 9 are partially responsive but remain incomplete. These requests ask Defendants to admit that “[J&J], Janssen Biotech, Janssen Oncology, and Janssen Research & Development collectively sell Zytiga pursuant to NDA No. 202379[.]” (Request No. 7), and to admit that “[J&J] arranged for the sale of Zytiga through its wholly owned subsidiaries, including the Janssen [Defendants] and their affiliates[.]” (Request No. 9). However, J&J’s responses only admit that J&J sold Zytiga “by and through its subsidiaries”, without admitting or denying whether any of the Janssen Defendants sold Zytiga or were otherwise involved in sales of Zytiga. In that respect, the Special Master finds that Defendants’ responses are incomplete. Defendants are directed to serve amended responses to Request for Admission Nos. 7 and 9 admitting or denying (or partially admitting or denying, with an appropriate qualifying statement) whether each of the Janssen Defendants sold Zytiga pursuant to NDA No. 202379 and whether J&J arranged for Zytiga sales through the Janssen Defendants in particular.

Request for Admission Nos. 11 through 14 and Nos. 16 through 20. The Special Master cannot find that Defendants’ responses to Request for Admission Nos. 11 through 14 and Nos. 16 through 20 are insufficient. As an initial matter, Relator did not furnish copies of these requests, or Defendants’ responses, and merely stated in his submissions that these requests pertain to “a number of important issues in the case[.]”⁶ Moreover, Relator acknowledges that Defendants’

⁶ According to Defendants, Request for Admission No. 20 asks to “[a]dmit that Defendants did not disclose to the Patent Office any of the alleged factors for Zytiga’s commercial success set forth in paragraphs 84 and 87 of the Complaint” (ECF No. 349, p. 15.)

responses to these requests do contain denials (in addition to objections). Given the undeveloped motion record with respect to these particular requests, Relator's Application as to Request for Admission Nos. 11 through 14 and Nos. 16 through 20 is denied.

c. Defendants' Responses to Relator's Sixth Requests for Production.

Request for Production No. 88. The Special Master finds that Relator's Application as to Request for Production No. 88 should be denied. While the Special Master does not necessarily agree with Defendants' statement that non-insurance indemnity agreements are irrelevant, the Special Master is persuaded by Defendants' point that Relator failed to act with respect to a prior, nearly identical document request served by Relator. Rather than re-serving a duplicative request (i.e., Request for Production No. 88), the better approach would have been to meet and confer with Defendants as to the prior request, and seek any relief from the Court or Special Master as to that particular request. Ultimately, should the question of apportionment of liability among Defendants become a critical issue at a later juncture of the litigation, Relator may seek appropriate relief at that time from the Court or Special Master.

Request for Production No. 89. The Special Master finds that Defendants should either: (1) represent to Relator that all non-privileged documents and communications responsive to this request have been searched for and produced; or (2) conduct a search for any such documents and communications that are responsive to this request and produce those materials. The Special Master recognizes that Defendants have produced items responsive to this request, along with a prior, nearly identical request (i.e., Request for Production No. 53). However, to the extent Defendants have not represented that all responsive materials have been produced, in the Special Master's view, the search and production as to Request for Production No. 89 remains incomplete. Further, Defendants have not articulated any burden or exorbitant costs associated with completing

a search and production for responsive materials. On balance, these considerations weigh in favor of directing Defendants to make a representation of completeness, or alternatively, undertake a search limited to the balance of any responsive documents and communications with respect to this request.

f. Conclusion

For the reasons set forth above, Relator's Application is **GRANTED IN PART AND DENIED IN PART**.

As to Relator's Interrogatory No. 16, Defendants are directed to serve an amended response consistent with this Opinion within twenty (20) days of the entry of this Order.

As to Relator's Interrogatory No. 17, Relator may serve an amended Interrogatory No. 17 identifying a single Request for Admission as to which Relator seeks all facts on which an unqualified admission by Defendants is based within fourteen (14) days of the entry of this Order. Defendants shall serve a response to any amended Interrogatory No. 17 within fourteen (14) days of service of amended Interrogatory No. 17.

As to Relator's Interrogatory No. 23, Defendants are directed to serve an amended response consistent with this Opinion within twenty (20) days of the entry of this Order.

As to Relator's Interrogatory No. 24, Defendants are directed to serve an amended response consistent with this Opinion within twenty (20) days of the entry of this Order.

As to Relator's Interrogatory No. 25, Defendants are directed to serve an amended response consistent with this Opinion within twenty (20) days of the entry of this Order.

As to Relator's Request for Admission No. 1, Relator's request for relief is denied.

As to Relator's Request for Admission Nos. 2 through 4, Defendants are directed to serve amended responses as to Request Nos. 2, 3, and 4 consistent with this Opinion within twenty (20) days of the entry of this Order.

As to Relator's Request for Admission No. 6, Relator may serve an amended Request for Admission No. 6 that includes a definition of the phrase, "real parties in interest" (or "real party in interest") within fourteen (14) days of the entry of this Order. Defendants shall serve a response to any such amended Request for Admission No. 6 which response shall be based on the definition of "real parties in interest" (or "real party in interest") within fourteen (14) days of service of amended Request for Admission No. 6.

As to Relator's Request for Admission Nos. 7 and 9, Defendants are directed to serve amended responses to these requests consistent with this Opinion within twenty (20) days of the entry of this Order.

As to Relator's Request for Admission Nos. 11 through 14 and Nos. 16 through 20, Relator's requests for relief are denied.

As to Relator's Request for Production No. 88, Relator's request for relief is denied.

As to Relator's Request for Production No. 89, Defendants are directed to either: (1) represent to Relator that all non-privileged documents and communications responsive to this request have been searched for and produced; or alternatively, (2) conduct a search for all non-privileged documents and communications responsive to this request that have not been produced in discovery, and produce all such responsive materials. Defendants shall comply with this provision and directive within thirty (30) days of the entry of this Order.

IT IS SO ORDERED.

Dated: October 22, 2024

s/ Douglas E. Arpert

DOUGLAS E. ARPERT
SPECIAL MASTER